

R E M A R K S

Entry of this Amendment and reconsideration of this application as amended are respectfully requested.

Claims 1-11, 26-28 and 78-136 are pending in this application, claims 12-25 and 29-77 having been canceled. Claims 110 and 111 are amended and the changes to the claims do not relate to patentability. Further, the changes to claims 110 and 111 do not raise a new issue and therefore, this amendment should be entered.

There are no prior art rejections of claims 89 and 96 but they have not been indicated as being allowable. Clarification of the status of claims 89 and 96 is respectfully requested in the next communication.

CLAIM REJECTIONS

LAWES

Claims 1-6, 78-82, 86-88, 97-103, 105, 106, 110-120, 122 and 123 were rejected as being anticipated by Lawes (USP 5,454,813) and claims 83-85, 107-109, 124-130 and 132-136 were rejected as being unpatentable over Lawes.

The Examiner's rejections are respectfully traversed because Lawes does not disclose, teach or suggest the present claimed invention. Each independent claim and the claims dependent therefrom are addressed separately below.

Claims 1-6 and 83-88

Independent claim 1 includes the feature of at least one sleeve comprising a locking mechanism which engages a portion of a nail around a respective hole when the sleeve is inserted therein, and which locking mechanism is integral with the sleeve and structured and arranged to cooperate with the portion of the nail around the respective hole to prevent rotational and longitudinal movement between the sleeve and the nail when the sleeve is inserted in the respective hole in the nail.

In the present claimed invention, the sleeve 50 includes an integral locking mechanism 51 which has a tab 52 on a depressible tongue 54 (see Fig. 3). The tab 52 engages with a notch 72 in the portion of the nail 32 around the sleeve 50 (shown in Fig. 2B) when the sleeve 50 is inserted into the hole 36 in the nail 32. Thus, the integral locking mechanism engages with the nail at a portion around the hole in the nail and this engagement prevents rotational and longitudinal movement between the sleeve and the nail.

Lawes does not disclose, teach or suggest a sleeve having an integral locking mechanism which cooperates with a portion of the nail around the hole into which the sleeve is inserted in order to prevent longitudinal movement between the sleeve and the nail.

In the Office Action, the Examiner states that the "notches prevent the rotation of the sleeve and the shoulder prevents

further longitudinal movement into the hole in the nail" (page 7). The notches in the Lawes device are designated 13a while the shoulder is designated 16. When the sleeve 12 is inserted into the hole 2 in the nail 1, notches 13a engage a portion of the nail 1 around the hole 2.

In contrast to the present claimed invention, no part of the Lawes device can be considered an integral locking mechanism which engages a portion of a nail around a hole into which the device is inserted and cooperates with this portion to prevent longitudinal movement between the sleeve and the nail. Notches 13a, while they engage with the portion of the nail around the hole, do not prevent longitudinal movement between the sleeve and the nail. Shoulder 13 does not engage and cooperate with the portion of the nail around the hole, i.e., the interior surfaces of the nail which define the hole. Rather, shoulder 16 appears to contact a small portion of the side of the nail and has absolutely no contact with the interior surfaces in the nail around the hole.

In any event, shoulder 16 is incapable of preventing longitudinal movement between the sleeve and the nail because the sleeve can freely move longitudinally outward away from the nail. Thus, longitudinal movement between the sleeve and the nail is not prevented by the shoulder 16.

Since Lawes does not disclose a sleeve which comprises an integral locking mechanism which engages and cooperates with a portion of the nail around a hole into which the sleeve is inserted, it cannot anticipate or render obvious the embodiment of the invention set forth in claim 1, or the embodiments set forth in claims 2-6 and 83-88 which depend directly or indirectly from claim 1.

Moreover, Lawes does not disclose, teach or suggest all of the features of dependent claims 2-6 and 83-88. For example, Lawes does not disclose a depressible male coupling element or tongue on the sleeve as set forth in claims 3 and 86. The Examiner referred to element 13 in Lawes but element 13 designates ridges formed on the outer surface of the sleeve 12 which cannot be depressed, i.e., pushed inward toward an axis of the sleeve.

Claims 78-82 and 134-136

Independent claim 78 includes the feature of an intra osseal body including at least one head hole therein and a retrieving device with "a portion of the retrieving device being lockable into the at least one hole in the body". The retrieving device is a device used to locate the body in the bone and to enable access to the body while the body is in the bone (as set forth claim 78).

Lawes does not disclose, teach or suggest a retrieving device which performs the recited functions in claim 78 and which also has a portion lockable into a hole in an intra osseal body insertable inside a bone as set forth in claim 78. Rather, Lawes shows a fitting device 31 and a tunnel locator 32. No part of either the fitting device 31 or the tunnel locator 32 is lockable into the opening 2 in the nail 1, or any other hole in the nail 1.

In the Office Action, the Examiner stated that "[a]s for Lawes not lockable into the angulated opening in the nail is a moot point because this is not even claimed in claim 78" (page 7). However, claim 78 includes the feature of the retrieving device having a portion lockable into a hole in an intra osseal body.

Since Lawes does not disclose a retrieving device which has a portion lockable into a hole in an intra osseal body, it cannot anticipate or render obvious the embodiment of the invention set forth in claim 78, or the embodiments set forth in claims 79-82 and 134-136 which depend directly or indirectly from claim 78.

Moreover, Lawes does not disclose, teach or suggest all of the features of dependent claims 79-82 and 134-136. For example, Lawes does not disclose a plurality of connecting elements on a retrieving device as set forth in claim 134.

Claims 97-103 and 105-113

Independent claim 97 includes the feature of locking means arranged on each sleeve for locking the sleeve in connection with a nail when the sleeve is inserted therein in order to prevent rotational and longitudinal movement between the sleeve and the nail.

In the present claimed invention, the locking means may comprise the locking mechanism 51 which has a tab 52 on a depressible tongue 54 which engages and cooperates with a notch 72 in the portion of the nail 32 around the sleeve 50 in order to prevent rotational and longitudinal movement between the sleeve and the nail.

Lawes does not disclose, teach or suggest such locking means. In particular, the device of Lawes is devoid of any depressible tongue on which a tab is formed whereby the tongue can be depressed inward during insertion of the sleeve into engagement with the nail and then flexes outward once the tab reaches a notch formed around the hole in the nail into which the sleeve is inserted, with the formation of the tab and its cooperation with the notch serving to prevent rotational and longitudinal movement between the sleeve and the nail.

Although Lawes includes notches 13a which project upward from the outer surface of the sleeve 12 and a shoulder 16 which extends around one end of the sleeve 12, the notches 13a and

shoulder 16 do not engage and cooperate with a notch formed in a portion of the nail 1 around the hole into which the sleeve 12 is inserted in order to prevent rotational and longitudinal movement between the sleeve 12 and the nail 1.

Since Lawes does not disclose structure which constitutes the locking means in accordance with the invention set forth in claim 97, it cannot anticipate or render obvious the embodiment of the invention set forth in claim 97, or the embodiments set forth in claims 98-103 and 105-113 which depend directly or indirectly from claim 97.

Moreover, Lawes does not disclose, teach or suggest all of the features of dependent claims 98-103 and 105-113. For example, Lawes does not disclose a flexible male coupling element on the sleeve as set forth in claim 102 or a depressible tongue as set forth in claim 110. The Examiner referred to element 13 in Lawes but element 13 designates ridges formed on the outer surface of the sleeve 12 which is not flexible and cannot be depressed, i.e., pushed inward toward an axis of the sleeve.

Claims 114-120, 122 and 123

Independent claim 114 includes the feature of a cooperating locking arrangement having a first part arranged on each sleeve and a second part formed in the nail for locking the sleeve in connection with the nail when the sleeve is inserted therein in

order to prevent rotational and longitudinal movement between the sleeve and the nail.

In the present claimed invention, the first part of the cooperating locking arrangement may comprise locking mechanism 51 which has a tab 52 on a depressible tongue 54 while the second part formed in the nail may comprise a notch 72 in the portion of the nail 32 around the sleeve 50. The presence of tab 52 in notch 72 prevents rotational and longitudinal movement between the sleeve and the nail.

Lawes does not disclose, teach or suggest a locking arrangement which has a second part formed in the nail and cooperates with a first part arranged on a sleeve to lock the sleeve in connection with the nail in order to prevent rotational and longitudinal movement between the sleeve and the nail.

Although Lawes includes notches 13a which project upward from the outer surface of the sleeve 12 and engage slots in the nail, the notches do not prevent longitudinal movement between the sleeve and the nail. Lawes also includes a shoulder 16 which extends around one end of the sleeve 12 and is alleged by the Examiner to prevent longitudinal movement. However, shoulder 16 does not cooperate with a part formed in the nail and thus cannot constitute a "second part" of a cooperating locking arrangement which locks the sleeve in connection with a nail in order to

prevent rotational and longitudinal movement between the sleeve and the nail as set forth in claim 114.

Since Lawes does not disclose structure which constitutes the cooperating locking arrangement set forth in claim 114, it cannot anticipate or render obvious the embodiment of the invention set forth in claim 114, or the embodiments set forth in claims 115-120, 122 and 123 which depend directly or indirectly from claim 114.

Moreover, Lawes does not disclose, teach or suggest all of the features of dependent claims 115-120, 122 and 123. For example, Lawes does not disclose a flexible male coupling element on the sleeve as set forth in claim 119. The Examiner referred to element 13 in Lawes but element 13 designates ridges formed on the outer surface of the sleeve 12 which cannot be depressed, i.e., pushed inward toward an axis of the sleeve.

Claims 124-130, 132 and 133

Independent claim 124 includes the feature of a locking mechanism which is structured and arranged to cooperate with a portion of a nail around a respective hole when the sleeve is inserted therein to restrict rotational and longitudinal movement between the sleeve and the nail.

Lawes does not disclose, teach or suggest a sleeve having an locking mechanism which cooperates with a portion of the nail

around the hole into which the sleeve is inserted in order to restrict longitudinal movement between the sleeve and the nail.

Lawes shows notches 13a on sleeve 12, but while notches 13a engage with the portion of the nail around the hole, they do not restrict longitudinal movement between the sleeve and the nail. Shoulder 16 does not cooperate with the portion of the nail around the hole. Rather, shoulder 16 appears to contact a small portion of the side of the nail 1 and has absolutely no contact with the interior surface in the nail 1 defined around the hole 2.

Since Lawes does not disclose a sleeve which comprises a locking mechanism which cooperates with a portion of the nail around a hole into which the sleeve is received to restrict rotational and longitudinal movement between the sleeve and the nail, it cannot anticipate or render obvious the embodiment of the invention set forth in claim 124, or the embodiments set forth in claims 125-130, 132 and 133 which depend directly or indirectly from claim 124.

Moreover, Lawes does not disclose, teach or suggest all of the features of dependent claims 125-130, 132, 133. For example, Lawes does not disclose a depressible tongue as set forth in claim 128. The Examiner referred to element 13 in Lawes but element 13 designates ridges formed on the outer surface of the

sleeve 12 which cannot be depressed, i.e., pushed inward toward an axis of the sleeve.

In view of the foregoing, it is respectfully submitted that the Examiner's rejections of claims 1-6, 78-88, 97-103, 105-120, 122-130 and 132-136 as being anticipated by or unpatentable over Lawes have been overcome and should be removed.

BRAMLET

Claims 7, 11, 26-28 and 95 were rejected as being anticipated by Bramlet et al (USP 6,648,889) and claims 8-10 and 90-94 were rejected as being unpatentable over Bramlet et al.

The rejections of claims 7-11, 26-28 and 90-95 are respectfully traversed because Bramlet et al does not disclose, teach or suggest the present claimed invention. Each independent claim and the claims dependent therefrom are addressed separately below.

Claims 7-11 and 90-95

Independent claim 7 includes the feature of the nail comprising a stem adjacent a first end of the nail and a proximal head having a distal portion including at least one hole for receiving a coupling element and a proximal portion. The distal portion is arranged adjacent the stem and the proximal portion is arranged adjacent a second end of the nail opposite the first end of the nail such that the distal portion of the head is between the proximal portion of the head and the stem. The proximal

portion has a diameter less than or equal to about 80% of the diameter of the distal portion.

In this embodiment of the present invention, the distal portion includes one or more holes which extend through the distal portion from one side to the other, i.e., a through hole.

Bramlet et al does not disclose, teach or suggest a nail having this construction.

In the Examiner's annotated drawing of Bramlet, the Examiner does not consider the entire portion of the proximal head in which the hole is formed to be the distal portion. Rather, the Examiner appears to designate part of the hole as being in the distal portion and another part of the hole in the proximal portion. This construction does not comport with the language of claim 7 which recites that it is distal portion which includes the at least one hole. If the entire portion of the head of Bramlet et al. which includes the hole is considered the distal portion, as it should be, then there is no proximal portion of the head which has a smaller diameter than a distal portion of the head as set forth in claim 7.

Since Bramlet et al does not disclose a nail having a proximal portion of a head which is smaller than a distal portion of the head, it cannot anticipate or render obvious the embodiment of the invention set forth in claim 7, or the

embodiments set forth in claims 8-11 and 90-95 which depend directly or indirectly from claim 7.

Claims 26-28

Independent claim 26 includes the feature of the nail comprising a stem adjacent a first end of the nail and a proximal head having a distal portion including at least one hole for receiving at least one coupling element and a proximal portion. The distal portion is arranged adjacent the stem and the proximal portion is arranged adjacent a second end of the nail opposite the first end of the nail. The proximal portion is visually discrete from the distal portion, e.g., visually and structurally distinct.

In this embodiment of the present invention, the distal portion includes one or more holes which extend through the distal portion from one side to the other, i.e., a through hole.

Bramlet et al does not disclose, teach or suggest a nail having this construction.

As argued above, the Examiner has not consider the entire portion of the proximal head of the Bramlet et al device in which the hole is formed to be the distal portion. Rather, the Examiner designated part of the hole as being in the distal portion and another part of the hole in the proximal portion. This construction does not comport with the language of claim 26 which recites that it is distal portion which includes the at

least one hole. If the entire portion of the head of Bramlet et al which includes the hole is considered the distal portion, as it should be, then there is no proximal portion of the head which is visually discrete from distal portion.

Since Bramlet et al does not disclose a nail having a proximal portion of a head which is visually discrete from a distal portion of the head, it cannot anticipate or render obvious the embodiment of the invention set forth in claim 26, or the embodiments set forth in claims 27 and 28 which depend from claim 26.

In view of the foregoing, it is respectfully submitted that the Examiner's rejections of claims 7-11, 26-28 and 90-95 as being anticipated by or unpatentable over Bramlet et al have been overcome and should be removed.

CONCLUSION

In view of the foregoing, it is respectfully submitted that claims 1-11, 26-28, 78-103, 105-120, 122-130 and 132-136 patentably distinguish over the prior art of record under 35 USC 102 and 35 USC 103. Therefore, applicant respectfully requests withdrawal of the rejections of these claims.

ALLOWABLE SUBJECT MATTER

____The Examiner's indication of allowable subject matter in claims 104, 121 and 131 is gratefully appreciated.

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If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,

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